

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0729]

DMP

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Publication Date	<i>2-7-02</i>
Certifier	<i>A. Corbin</i>

Medical Devices; Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revision to the draft guidance entitled "Guidance on the Content and Format of Premarket Notification (510(k)) Submission of Washers and Washer-Disinfectors." (63 FR 59794). The revised guidance renamed "Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors" will serve as a special control for medical washers and medical washer-disinfectors if they are classified into class II. Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule to classify medical washers as class II (special controls).

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors" to the Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified

with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Chiu Lin, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913.

SUPPLEMENTARY INFORMATION:

I. Background

The intent of this guidance document for class II medical washers and medical washer-disinfectors is: (1) To provide applicants specific directions regarding information and data that should be submitted to FDA in a 510(k) submission for medical washer-disinfectors intended to clean and provide high level disinfection, and (2) to provide recommendations on information and data to be held as part of the design control record for a medical washer intended to clean medical devices or a medical washer-disinfector intended to clean and provide either a low or intermediate level of disinfection for medical devices. The General Hospital and Personal Use Devices Advisory Panel met on September 14, 1998, and unanimously recommended that the medical washer and washer-disinfector be classified into class II.

FDA made the draft guidance entitled “Guidance on the Content and Format of Premarket Notification (510(k)) Submissions of Washers and Washer-Disinfectors” available for comment on November 5, 1998 (63 FR 59794). The public comment period closed February 3, 1999. FDA reviewed the comments and revised the draft guidance as appropriate. The final guidance renamed “Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors” replaces the November 5, 1998, draft.

II. Significance of Guidance

This guidance document represents the agency’s current thinking on medical washers and medical washer-disinfectors. It does not create or confer any rights for or on any person and does

not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This guidance document is issued as level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

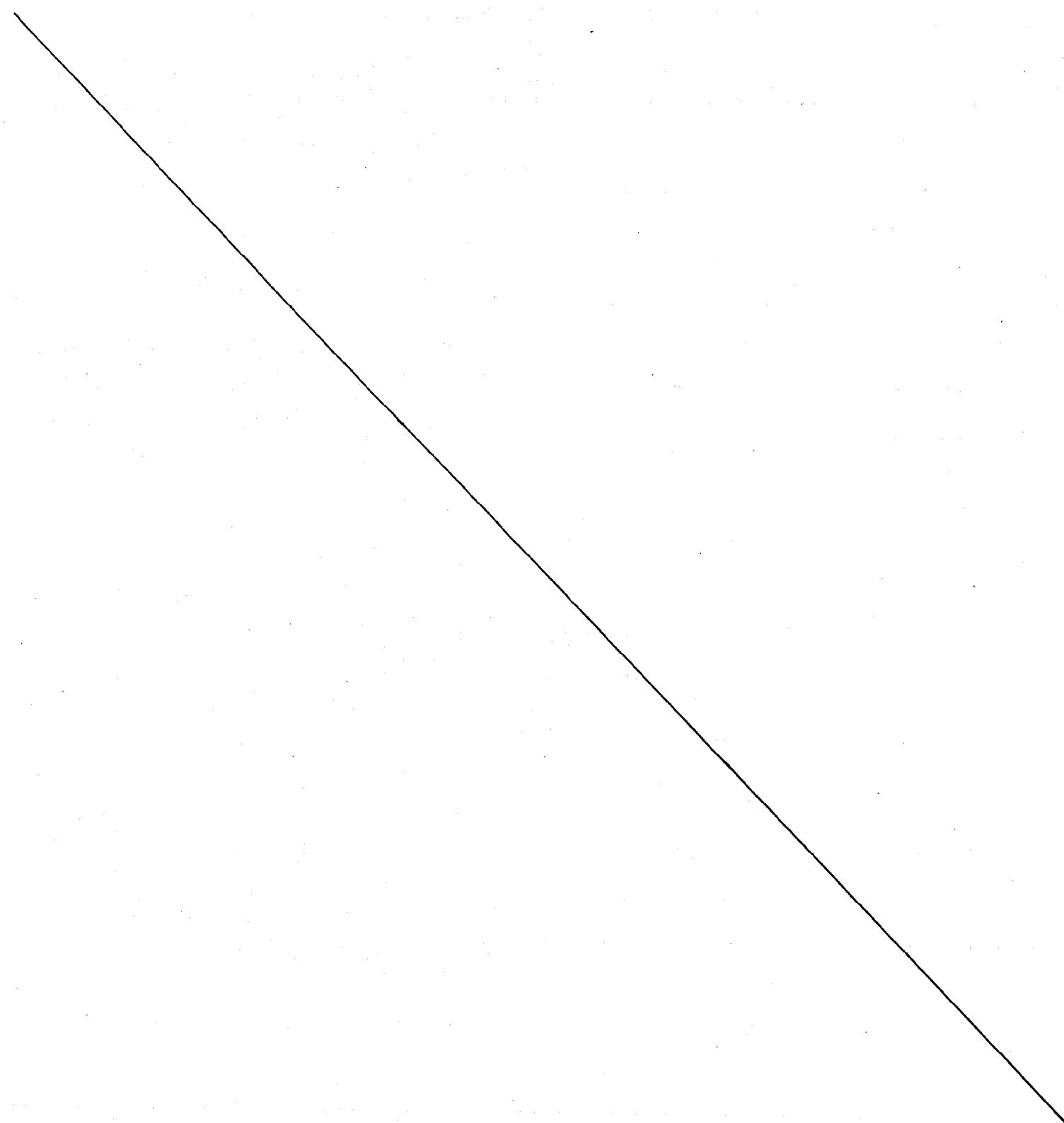
In order to receive "Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 1252 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this guidance at any time. Submit two copies of any comments,

except that individuals may submit one copy. Comments are to be **identified** with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 8/24/01

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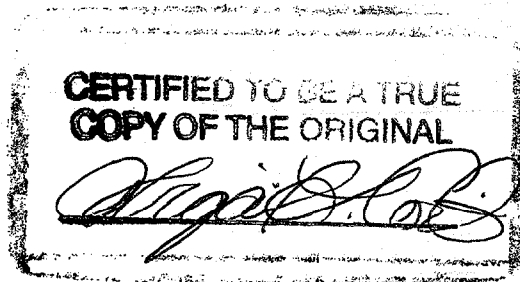
August 24, 2001.

Linda S. Kahan

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